From:	Kunickis, Sheryl - OSEC
To:	Schroeder, Jill; Hill2, Elizabeth - ARS; Chin, Teung; Domesle, Alexander - ARS; Abbott, Linda - OCE; Fajardo, Julius; Schechtman, Michael; Epstein, David
Subject:	Fwd: PPDC Agenda and Materials
Date:	Friday, October 21, 2016 2:10:54 PM
Attachments:	Final Agenda for November 2016 PPDC Meeting.docx ATT00001.htm Session 7b ESA Implementation Update.docx ATT00002.htm Session 7c Epi Framework Update.docx ATT00003.htm Session 7d PRIA 4 Update.docx ATT00004.htm Session 7e Resistance Management Update.docx ATT00005.htm Session 7f Chlorpyrifos Update.docx ATT00006.htm Session 7g Glyphosate Update.docx ATT00007.htm

---

Looks like a loaded agenda. I can already think of questions for the items listed below! C&T is a topic - could be interesting. DO NOT SHARE this copy. While it will be out, I don't want anyone to say USDA shared it.
Cheers,
Sheryl

Sent from my iPad

Begin forwarded message:

From: "Zimmerman, Dea" <Zimmerman.Dea@epa.gov>
Date: October 21, 2016 at 1:59:18 PM EDT
To: Undisclosed recipients:;
Subject: PPDC Agenda and Materials

Dear PPDC Members –

Attached please find the agenda for the November 2-3 PPDC meeting taking place in the first floor conference center in the Potomac Yards South building located at 2777 S. Crystal Drive, Arlington, VA 22202.

Similar to the May 2016, there is a session at 9:00 am on Thursday November 3rd, where OPP managers and staff will be available to discuss questions you may have on selected topics. The session is:

9:00-10:30 7. Question and Answer Session to Topic Updates Sent in Advance of Meeting

Session Chairs: *OPP Senior Leadership Team*

Session Goal: *Answer questions from PPDC members on:*

<!--[if !supportLists]-->*a.* <!--[endif]--> *Acute 6-Pack Testing Alternatives*

<!--[if !supportLists]-->*b.* <!--[endif]-->*Endangered Species Act Implementation Update*
<!--[if !supportLists]-->*c.* <!--[endif]-->*Epidemiological Framework*
<!--[if !supportLists]-->*d.* <!--[endif]-->*Pesticide Registration Improvement Act (PRIA) 4*
<!--[if !supportLists]-->*e.* <!--[endif]-->*Resistance Management*
<!--[if !supportLists]-->*f.* <!--[endif]-->*Chlorpyrifos*
<!--[if !supportLists]-->*g.* <!--[endif]-->*Glyphosate*

OPP has prepared summaries for each topic, all of which are attached except the "Acute 6-Pack Testing Alternatives". I will pass this one along by early next week at the latest. Please review these materials in advance of the meeting and come prepared with any questions you may have.

I will also post presentation materials for the rest of the sessions to the PPDC website, hopefully by mid-week, and let you know when that is done.
https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc

Entering Potomac Yards – please give yourself some extra time.
As a reminder and for those who have never been to Potomac Yards, you will need to go thru security screening to enter the building. You will need to present photo identification to the security guards, sign in and go through the metal scanners. Due to the REAL ID Act, Driver's licenses may not be accepted from **Minnesota, Missouri and Washington** (people from these states can use a passport or an official state identification badge). You do not need an escort for the full PPDC meeting happening in the lobby level conference room. I will give the buidling security guards a list with your name on it to try to expedite your entrance.

If something has come up and you will not be attending the PPDC, please let me know (regrets only). Also please let me know if you will be participating remotely by phone. Safe travels and I look forward to seeing everyone.

Regards,

Dea

Dea Zimmerman
Pesticide Program Dialogue Committee, DFO
Zimmerman.dea@epa.gov
312-353-6344

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA
Conference Line: 1-866-299-3188; Conference Code: 312-353-6344 #

Wednesday, November 2, 2016

9:00-9:20 ***Welcome and Opening Remarks***
Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention
Jack Housenger, Director, Office of Pesticide Programs

9:20-9:30 ***Introductions by PPDC Members***

9:30-10:30 ***1. OPP's Role in Agricultural Biotechnology Today and Tomorrow***
Session Chair: *Robert McNally, Director, Biopesticides and Pollution Prevention Division*
Mike Mendelsohn, Senior Regulatory Advisor, BPPD
Elizabeth Milewski, Senior Science Advisor, BPPD
Session Goal: *Discuss new technologies for pest control and the role the government, and specifically OPP, will play in ensuring adequate regulation.*
9:30-10:00 EPA
10:00-10:30 PPDC Discussion

10:30-10:45 ***Break***

10:45-11:45 ***2. Zika Update***
Session Chair: *Arnold E. Layne, Deputy Director, Office of Pesticide Programs*
Session Goal: *Provide an update on OPP's activities since May and discuss regulatory challenges to address the issue of mosquito control.*
10:45-11:00 EPA
11:00-11:45 PPDC Discussion

11:45-1:15 ***Lunch***

1:15-2:15 ***3. Pollinator Protection Updates: Acute Bee Mitigation Proposal and Neonicotinoid Risk Assessment Schedule***
Session Chairs*: Michael Goodis, Acting Director, Registration Division*
Yu-Ting Guilaran, Director, Pesticide Re-evaluation Division
Marietta Echeverria, Chief, Invertebrate-Vertebrate Branch I, Registration Division
Session Goal: *Provide an update on the acute bee mitigation proposal and the risk assessment schedule for the neonicotinoid active ingredients.*
1:15-1:45 EPA
1:45-2:15 PPDC Discussion

2:15-2:45 ***4. Update from the Pollinator Protection Plan Metrics Workgroup***
Session Chair: *Michael Goodis, Acting Director, Registration Division*

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING – p. 2

Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA
Conference Line: 1-866-299-3188; Conference Code: 312-353-6344 #

***Session Goal**: Provide the PPDC a current status of this workgroup.*
2:15-2:30 EPA
2:30-2:45 PPDC Discussion

2:45-3:00 Break

3:00-3:45 5. Updates on the Certification of Pesticide Applicators Rule and Implementation Activities of the Revised Worker Protection Standard
***Session Chair:** Kevin Keaney, Chief, Certification and Worker Protection Branch, Field and External Affairs Division*
***Session Goal:** Discuss the Agency's ongoing efforts to protect farmworkers through updates on the progress for implementing the Worker Protection Standard Rule and for finalizing the Certification of Pesticide Applicators Rule.*
3:00-3:15 EPA
3:15-3:45 PPDC Discussion

3:45-4:30 6. a. Update on Dicamba Registration
b. Synergy Claims
***Session Chair:** Dan Kenny, Chief, Herbicide Branch, Registration Division*
***Session Goal:** Provide an update on the pending registration of dicamba on herbicide tolerant cotton and soybeans and discuss the implications of synergy patent claims on new registrations.*
3:45-4:00 EPA
4:00-4:30 PPDC Discussion

4:30-4:45 Public Comment

4:45 Meeting Adjourns

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING – p. 3

Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA
Conference Line: 1-866-299-3188; Conference Code: 312-353-6344 #

Thursday, November 3, 2016

9:00-10:30 ***7. Question and Answer Session to Topic Updates Sent in Advance of Meeting***
Session Chairs: *OPP Senior Leadership Team*
Session Goal: *Answer questions from PPDC members on:*

a. *Acute 6-Pack Testing Alternatives*
b. *Endangered Species Act Implementation Update*
c. *Epidemiological Framework*
d. *Pesticide Registration Improvement Act (PRIA) 4*
e. *Resistance Management*
f. *Chlorpyrifos*
g. *Glyphosate*

10:30-10:45 ***Break***

10:45-11:15 ***8. Update from the Pesticide Incidents Workgroup***
Session Chair: *Jackie Mosby, Director, Field and External Affairs Division*
Session Goal: *Provide an update on accomplishments since May.*
10:45-11:00 EPA
11:00-11:15 PPDC Discussion

11:15-11:45 ***9. Discussion of Agenda Topics for Next Meeting***
Session Chair: *Jack Housenger, Director, Office of Pesticide Programs*
Session Goal: *Discuss topic areas where PPDC members or OPP feels would be beneficial to have on the next agenda.*

11:45-12:00 ***Public Comment***

12:00 ***Meeting Adjourns***

ENDANGERED SPECIES ACT (ESA) IMPLEMENTATION UPDATE
PPDC Meeting Nov. 2, 2016 – Session 7b

- Based on recommendations from the 2013 National Academy of Sciences' report "Assessing Risks to Endangered and Threatened Species from Pesticides" EPA has been working closely with the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (collectively referred to as the Services) to develop shared interim scientific methods for use in pesticide consultations.
- EPA released draft Biological Evaluations (BEs) for three pilot chemicals including chlorpyrifos, diazinon, and malathion in April 2016. Following a 60-day public comment, EPA received over 78,600 comments with about 120 substantive comments meriting detailed review.
- In June 2016, EPA and Services held a two-day meeting that provided a forum for stakeholder suggestions for refining some of the interim scientific methods used in the April 2016 draft BEs. The meeting included opening and closing plenary sessions and breakout sessions intended to address inter-agency developed charge questions related to potential refinements for aquatic modeling, spatial and non-spatial refinements to Step 2 (i.e., EPA's determination of "likely to adversely affect" or "not likely to adversely affect"), and refinements to the weight-of-evidence (WoE) approach for plants and animals. Meeting materials including the agenda, charge questions, the opening plenary presentations, and the closing plenary reports are available at: https://www.epa.gov/endangered-species/5th-esa-workshop-joint-interim-approaches-nas-recommendations. EPA and the Services have reviewed the recommendations and identified those that can be addressed in the short-, mid-, and long-term.
- Recommendations from the June 2016 stakeholder meeting and public comments on the draft BEs for the three pilot chemicals will be addressed in a phased approach, given consultation deadlines and existing resources.
- In September 2016, EPA and the Services held a 3-day workshop to continue work on interim methods and tools for use in Step 3 (i.e., the Services' determination of "jeopardy/adverse modification" or "no jeopardy/no adverse modification" in the BiOp).
- Final BEs for the three pilot chemicals are expected to be released in mid-January 2017.
    - Although this date is one month later than originally anticipated, the January 2017 release of the final BEs will not impact the Services draft Biological Opinion (BiOp) deadline, given that EPA will provide the Services with any additional data needs in sufficient time for integration into the draft BiOp.
    - Expected revisions to the final BEs based on stakeholder feedback will include refined aquatic modeling, error corrections, improved transparency specifically related to the Terrestrial Effects Determination (TED) tool and the WoE matrices, and additions/deletions to the list of endangered and threatened species.
    - Other comments being considered for future BEs include: reducing the size and complexity of the BEs, moving toward more probabilistic approaches, exploring ways to better screen species with little or no risk while still being protective, refining species range maps and potential use sites, exploring use of watershed-level aquatic models, and considering the timing of potential exposure (e.g., linkage with life-history variables) and potential durations of exposure.
- Draft BEs for carbaryl and methomyl are expected to be released for public comment in the spring of 2017.
- The Services expect to release draft BiOps for the three pilot chemicals for public comment in the spring of 2017 with final BiOps by December 2017. Final BiOps for methomyl and carbaryl will be released in December 2018.

October 15, 2016

Draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment"
PPDC Meeting Nov. 2, 2016 – Session 7c

In 2010, OPP developed a draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" which provides the foundation for evaluating multiple lines of scientific evidence in the context of the understanding of the adverse outcome pathway (or mode of action (U.S. EPA, 2010). The draft framework, which includes two key components: problem formulation and use of the Mode of Action/Adverse Outcome Pathway (MOA/AOP) frameworks, was reviewed favorably by the SAP in 2010 (FIFRA SAP, 2010).

OPP's draft framework is consistent with updates to the World Health Organization/International Programme on Chemical Safety mode of action/human relevance framework, which highlight the importance of problem formulation and the need to integrate information at different levels of biological organization[1]. Consistent with recommendations by the NRC in its 2009 report on *Science and Decisions*[2], OPP's draft framework describes the importance of using problem formulation at the beginning of a complex scientific analysis. The problem formulation stage starts with planning dialogue with risk managers to identify goals for the analysis and possible risk management strategies. This initial dialogue provides the regulatory context for the scientific analysis and helps define the scope of such an analysis. The problem formulation stage also involves consideration of the available information regarding the pesticide use/usage, toxicological effects of concern and exposure pathways and duration along with key gaps in data or scientific information.

MOA and AOP provide important concepts in this integrative analysis. Both a MOA and an AOP are based on the premise that an adverse effect caused by exposure to a compound can be described by a series of causally linked biological key events that result in an adverse human health or ecological outcome. One of the key components of the Agency's draft framework is the use the MOA framework /AOP concept as a tool for organizing and integrating information from different sources to inform the causal nature of links observed in both experimental and observational studies. Specifically, the modified Bradford Hill Criteria are used to evaluate the experimental support that establishes key events within a mode of action or an adverse outcome pathway, and explicitly considers such concepts as strength, consistency, dose response, temporal concordance and biological plausibility in a weight of evidence analysis.

---

[1] Meek ME, Boobis A, Cote I, Dellarco V, Fotakis G, Munn S, Seed J, Vickers C. 2014. New developments in the evolution and application of the WHO/IPCS framework on mode of action/species concordance analysis. J Appl Toxicol. 2014 Jan;34(1):1-18.

[2] NRC (National Research Council). (2009). Science and decisions: Advancing risk assessment. Washington, DC: The National Academies Press. http://www.nap.edu/openbook.php?record_id=12209

One of the recommendations of the SAP was to gain experience integrating epidemiology and human incident information into risk assessment in order to further refine the approach in the draft framework. Consistent with this recommendation, OPP did not finalize the draft framework after the 2010 SAP but instead has used in draft framework in several chemical risk assessments (atrazine, chlorpyrifos and other organophosphates, glyphosate) to gain experience. Through this experience, OPP has refined the proposed approach with an improved, more transparent grading system for epidemiology studies; the revised framework will include this grading system.

In recent years, the National Academies' National Research Council (NRC) has encouraged the agency to move towards systematic review processes to enhance the transparency of scientific literature reviews that support chemical-specific risk assessments to inform regulatory decision making[3]. The NRC defines systematic review as "a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies". OPP has been collaborating across the other offices in the Office of Chemical Safety and Pollution Prevention (OCSPP) to implement systematic review. The concepts associated with fit-for-purpose systematic review such as standard methods for collecting, evaluating and integrating the scientific data will also be included in the revised, final framework.

OPP is actively working on revising and finalizing the draft framework and anticipates release of the final document within the next few months.

[3] NRC 2011. "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde"; NRC 2014. "Review of EPA's Integrated Risk Information System (IRIS) Process"

Update on Changes to Maintenance Fees and PRIA 4
PPDC Meeting Nov. 2, 2016 – Session 7d

[These bullets reflect the status of PRIA 4 while we were providing technical advice to the PRIA Stakeholder Coalition during development, but we have not seen the actual Bill language being developed by Congress.]

Maintenance Fees

- Extends fees for 7 more years from FY'17 thru FY'23;
- Fees increased from $27.8M to $31.0M per year;
- Can average across years to correct for over or under collection in previous years during PRIA 4;
- Eliminates IT set-aside ($800,000 per year) to improve (a) electronic tracking of registration submissions, (b) electronic tracking of conditional registrations, (c) electronic review of labels, (d) electronic CSFs and (e) ESA database enhancements (but reporting on the unspent balance of PRIA 3 IT set-asides remains);
- Creates new $500,000 per year set-aside to support efficacy guideline development and rulemaking for invertebrate pests of significant public health and/or economic importance with a mandatory schedule of deliverables;
- Creates new $500,000 per year set-aside to support GLP inspections;

PRIA 4 (Pesticide Registration Enhancement Act of 2016)

- Extends PRIA for 7 more years from FY'17 thru FY'23;
- Increases the number of covered fee categories from 189 to 212; changes include but not limited to:
    - adds harmonization with Codex MRLs to existing category;
    - adds categories for pests requiring efficacy data and review;
    - adds new EUP categories for AD, BPPD and RD chemicals;
    - AD categories modified to be consistent with 158W;
    - adds unregistered source of AI category for BPPD;
    - adds new PIP categories;

  - adds new inert safener categories and lengthens certain inert category timeframes where warranted by their average completion times and the # of renegotiations;

- Enhances incentives for reduced-risk submissions by raising fees for the corresponding non-reduced risk categories (new conventional AIs and new uses);

- Eliminates small business waivers for Gold Seal letters;

- New reporting requirements:
  - identify reforms to streamline new AI and new use processes and provide prompt feedback to applicants during the process;
  - progress in meeting mandatory schedule in developing efficacy guidelines for invertebrate pests of significant public health and/or economic importance;
  - # of GLP inspections/audits conducted;
  - progress in priority review and approval of new pesticides to control vector borne pests in the U.S. including territories and military bases globally;
  - # of registration review cases completed, fully implemented, required mitigation

- Updates Section 5 on EUPs to be consistent with PRIA 4 timeframes.

EPA's Pesticide Registration Notices (PRNs) on Resistance Management
PPDC Meeting Nov. 2, 2016 – Session 7e

Background

Many pesticides have gradually lost their effectiveness over time because pests have developed resistance, a significant decrease in sensitivity to a pesticide, which reduces the field performance of these pesticides. The agency is concerned about resistance issues and believes that managing the development of pesticide resistance, in conjunction with alternative pest-management strategies and Integrated Pest Management (IPM) programs, is an important part of sustainable pest management. To address the growing issue of resistance and prolong the useful life of pesticides, the agency has initiated a more widespread effort that is aimed at combating and slowing the development of pesticide resistance. On June 3, 2016, the agency concurrently released and requested public comment on two draft Pesticide Registration Notices (PRNs) related to pesticide resistance. The public comment closed on September 1, 2016. The two PRNs include:

1. PRN 2016-X: Draft Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling. PRN 2016-X revises and updates PRN 2001-5, which is the agency's current guidance for pesticide resistance management labeling. This PRN applies to all agricultural pesticides except plant-incorporated protectants (PIPs), which are covered by a separate guidance issued by the Biopesticides and Pollution Prevention Division (BPPD). The updates in PRN 2016-X focus on pesticide labels and are aimed at improving information about how pesticide users can minimize and manage pest resistance.

2. PRN 2016-XX: Draft Guidance for Pesticide Registrants on Herbicide Resistance Management Labeling, Education, Training, and Stewardship. PRN 2016-XX applies only to herbicides. This PRN communicates the Agency's current thinking and proposes an approach to address herbicide-resistant weeds by providing guidance on labeling, education, training, and stewardship for herbicides undergoing registration review or registration. It is part of a holistic, proactive approach to slow the development and spread of herbicide-resistant weeds, and to prolong the useful lifespan of herbicides and related technology. The Agency is focusing on guidance for herbicides first because they are the most widely used agricultural chemicals, no new herbicide mechanism of action has been developed in the last 30 years, and the number of herbicide-resistant weed species and acres infested with resistant weeds have increased rapidly in recent years.

Current Status

The Agency is in the process of reviewing and addressing the public comments we received on these PRNs.

1. The Agency received 19 comment letters on the pesticide labeling PRN (2016-X) from non-governmental organizations (NGOs), grower groups, professional scientific societies, registrants, resistance action committees (RACs), and USDA. The main themes included the following:

A. General agreement that additional information on resistance management on labels would be useful – especially the routine inclusion of a pesticide's Mode of Action group as set by the various RACs.
B. A few RACs disagreed with some of the suggested label statements in the guidance, particularly for fungicides and insecticides. EPA is in the process of evaluating if and how these label statements should be altered based on these comments.
C. Some commenters expressed concern and confusion on: (1) whether non-agricultural pesticides are covered and (2) whether all of the guidance in this PRN is mandatory for registrants or pesticide users. EPA is in the process of reviewing these comments and will clarify these issues in the final version of the PRN.

2. The Agency received 27 comment letters on the herbicide resistance management PRN (2016-XX) from NGOs, crop groups, professional societies, registrants, RACs, and USDA. The main themes included the following:

A. General agreement that pesticide labels should provide additional resistance management information. A few commenters, however, did not agree that extensive resistance management language is appropriate for labels.
B. The Agency proposed three categories of concern (low, medium, high) based on the potential for weeds to develop herbicide resistance. The three categories proposed different approaches for resistance management in regards to labeling, education, training, and stewardship guidance. Most commenters recommended that all herbicides be grouped into a single category and treated as if there is high concern for resistance.
C. Many commenters were against having the registrants provide additional information to the user/grower (e.g. a separate lists of resistant weeds, additional reporting of resistant weeds, or resistance management plans).

Next Steps

The Agency is evaluating the public comments and expects to finalize both PRNs in late 2016. Also, the Agency plans to implement herbicide resistance measures for existing chemicals during registration review, and to implement herbicide resistance measures for new herbicides and new uses at the time of registration.

Chlorpyrifos Status Update for PPDC Meeting Nov. 2, 2016 – Session 7f Prepared: October 19, 2016

Background

The EPA must respond to a National Resources Defense Council (NRDC) and Pesticide Action Network of North America (PANNA) petition seeking the revocation of all chlorpyrifos tolerances and cancelation of all registrations for chlorpyrifos, citing human health concerns. In October 2015, the EPA issued a proposed tolerance revocation for chlorpyrifos based on the science as it stood. There are several unresolved scientific issues the EPA has been working through before issuing a final decision.

EPA has considered several approaches in determining the critical effect, and related uncertainties, for use in the chlorpyrifos human health risk assessment. The 2014 revised human health risk assessment used dose-response data on acetylcholinesterase inhibition (AChI) in laboratory animals to derive a point of departure. However, the EPA believes that evidence from epidemiology studies indicates effects may occur at lower exposures than indicated by the toxicology database. The EPA consulted with the FIFRA Scientific Advisory Panel (SAP) on using a specific epidemiology study to establish a new toxicological endpoint and associated point of departure for the chlorpyrifos risk assessment. The SAP advised against that approach. The SAP also emphasized concern that the point of departure based on AChI is not sufficiently health protective for use in risk assessment. The 2016 SAP cited that epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below these levels, which is consistent with recommendations from the 2012 SAP meeting on chlorpyrifos.

The EPA has thoroughly considered the SAP's recommendations, and is currently finalizing its 2016 revised risk assessment. The EPA anticipates making the revised risk assessment, along with an updated drinking water assessment, available for public comment in the very near future. The EPA anticipates issuing a final tolerance rule for chlorpyrifos by the court-ordered deadline, March 31, 2017.

Milestones

- The EPA anticipates issuing a Notice of Data Availability (NODA) for the proposed rule in the very near future. The NODA will include a revised human health risk assessment, updated drinking water assessment, and other supporting information. The EPA will also notify the World Trade Organization of EPA's impending tolerance decision at this time.
- The Notice of Data Availability will be published for a 60-day public comment period.
- The EPA will respond to public comments and finalize its decision on the chlorpyrifos tolerance rule by March 31, 2017.

Glyphosate Update
PPDC Meeting Nov. 2, 2016 – Session 7g

Overview

Glyphosate is a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings. Labeled uses of glyphosate include over 100 terrestrial food crops as well as other non-agricultural sites, such as greenhouses, aquatic areas, and residential areas. Use of glyphosate in the United States and globally has increased overtime, particularly with the introduction of glyphosate-resistant crops; however, usage has stabilized in recent years due to the increased number of weed species becoming resistant to glyphosate. Glyphosate is currently undergoing Registration Review, which reviews all registered pesticides at least every 15 years as mandated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Recently, EPA collected and analyzed a substantial amount of data informing the carcinogenic potential of glyphosate and utilized the draft "Framework for Incorporating Human Epidemiological & Incident Data in Health Risk Assessment", which provides the foundation for evaluating multiple lines of scientific evidence. A comprehensive analysis of data on glyphosate from submitted guideline studies and the open literature was performed. This includes epidemiological, animal carcinogenicity, genotoxicity, and absorption, distribution, metabolism, and excretion (ADME) studies. Guideline studies were collected for consideration from the toxicological databases for glyphosate and glyphosate salts. A fit-for-purpose systematic review was executed to obtain relevant and appropriate guideline and open literature studies with the potential to inform the human carcinogenic potential of glyphosate. Furthermore, the list of studies obtained from the toxicological databases and systematic review was cross-referenced with recent internal reviews, review articles from the open literature, and international agency evaluations.

Available data from epidemiological, animal carcinogenicity, and genotoxicity studies were reviewed and evaluated for study quality and results to inform the human carcinogenic potential of glyphosate according to the 2005 Guidelines for Carcinogen Risk Assessment. A total of 58 epidemiological studies, 20 animal carcinogenicity studies, and almost 200 genotoxicity assays were considered in the current evaluation. Additionally, multiple lines of evidence were integrated in a weight-of-evidence analysis using the modified Bradford Hill Criteria considering concepts, such as strength, consistency, dose response, temporal concordance, and biological plausibility. The totality of the data has been used by the agency to inform cancer classification descriptors according to the 2005 Guidelines for Carcinogen Risk Assessment. The agency originally planned to hold the FIFRA Scientific Advisory Panel (SAP) evaluation of human carcinogenic potential for the active ingredient glyphosate on October 18-21, 2016.

On October 14, 2016, EPA postponed the FIFRA SAP meeting due to recent changes in the availability of experts for the peer review panel. Given the importance of epidemiology in the review of glyphosate's carcinogenic potential, the agency believes that additional expertise in epidemiology will benefit the panel and allow for a more robust review of the data. As a result, the SAP meeting on glyphosate has been postponed. The agency will issue another announcement once the new date for the SAP meeting on glyphosate has been determined.

From:	Kunickis, Sheryl - OSEC
To:	Epstein, David; Fajardo, Julius; Schroeder, Jill; Hill2, Elizabeth - ARS; Chin, Teung; Domesle, Alexander - ARS
Subject:	FW: Brown Bag Seminar: University of Virginia Presentation on "AgroSpheres a particle that degrades residual pesticides on the surface of produce"
Date:	Tuesday, September 13, 2016 8:17:57 AM
Attachments:	AgroSpheres- synopsis.docx

See invitation. I could not access the Doodle poll on my desk top computer, but had no problems using the IPad. I have asked if it can be forwarded to USDA folks outside of OPMP.
Looks interesting.
Sheryl

From: Keigwin, Richard [mailto:Keigwin.Richard@epa.gov]
Sent: Tuesday, September 13, 2016 5:34 AM
To: Kunickis, Sheryl - OSEC
Subject: FW: Brown Bag Seminar: University of Virginia Presentation on "AgroSpheres a particle that degrades residual pesticides on the surface of produce"

OPMP is welcome to participate as well. I had reached out to Sally Schneider because she and I attended a seminar at NC State at the end of July and we had agreed that on these types of issues I would be sure to include her.

From: Keigwin, Richard
Sent: Friday, September 09, 2016 6:37 AM
To: Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Schneider, Sally <Sally.Schneider@ARS.USDA.GOV>; Grusak, Mike <Mike.Grusak@ARS.USDA.GOV>; Whalen, Maureen <Maureen.Whalen@ARS.USDA.GOV>; Hackett, Kevin <Kevin.Hackett@ARS.USDA.GOV>
Subject: Brown Bag Seminar: University of Virginia Presentation on "AgroSpheres a particle that degrades residual pesticides on the surface of produce"

As I mentioned to Leslie and Sally, EPA has been approached by two engineering students at the University of Virginia who would like to make a presentation to EPA, FDA, and USDA regarding a product that they've developed that may have the potential to degrade pesticide residues on produce. EPA is happy to host the presentation at our facility in Arlington, VA; people can also participate via teleconference. Please see the link below that connects to a Doodle poll in hopes of finding the best day that works for all three agencies. If you think others would be interested in hearing the presentation, please send the link to those individuals as well. If possible, please respond to the Doodle poll by COB next Friday (September 16th) so that the UVA students can make arrangements to travel to the DC area.

They've sent a backgrounder (attached) to provide you with some additional information about their project.

http://doodle.com/poll/334bzw8s2tsrpe6e

Rick Keigwin

Deputy Director for Programs
Office of Pesticide Programs
US Environmental Protection Agency

AgroSpheres: The future of Agriculture

AgroSpheres is a non-toxic, environmentally friendly biological particle that degrades residual pesticides on the surface of produce. This device was developed by engineering organophosphate hydrolase (OPH), an enzyme that degrades organophosphate pesticides, onto the surface of an E. coli cell. These E. coli cells were then induced to generate minicells (containing no endogenous genetic material), which retained the OPH on their surface membrane. The resultant product is a biological device that degrades paraoxon but does not proliferate in the environment. Preliminary proof of concept data suggests that we have engineered a minicell that contains functional, catalytically active OPH that degrades organophosphate pesticides on plants.

Initially, AgroSpheres is designed to target three big pain points for the agricultural industry as a whole and for wine producers specifically: exposure to pesticides leading to health risks, inflexible Pre Harvest Intervals (PHIs) that determine the minimum time after pesticide application before harvesting is allowed, and stuck fermentation resulting from residual pesticides killing the yeast during the fermentation process. The major value proposition of AgroSpheres is to degrade residual pesticides on demand, which alleviates the three major pain points for our target market. We have determined that we can use this same platform to degrade DDT, which is commonly used in developing countries to combat malaria-stricken mosquitoes. From our lab tests we have determined that there are other forms of remediation for AgroSpheres. They can be programmed to degrade and/or detect radiation, nerve gas, anthrax, and etc. There are countless applications for this platform technology.

Our biological particle is a modular platform technology that can be applied within many contexts; our robust intellectual property position is based upon the design of unique plasmids and unique applications. While the first proof of concept prototype has been developed to degrade organophosphate pesticides like Malathion, the first commercial product will be designed to degrade sprays such as Mancozeb, Captan, and Revus Top. Mancozeb is a cheap, broad spectrum pesticide that wine producers would love to use. Unfortunately, the PHI of Mancozeb is 66 days, which limits its use to the first half of the growing season. During the R&D of AgroSpheres, we will be building our expertise in our platform technology and of the regulatory landscape so that future agriculture and biotechnology applications will have a much lower barrier to entry.

Bacteria have several properties that would make them useful vectors: They are readily engineered, easily grown, and stable in the environment. However, the use of genetically modified bacteria in the environment is riddled with issues, such as the proliferation and horizontal gene transfer of engineered DNA. The biological particles are the result of aberrant cell division in bacteria that yields a normal parent cell and an achromosomal “cell”. Because they lack chromosomes, they cannot replicate, mutate, or express virulent bacteria genes. However, they still contain and express transfected plasmids, which mean that the biological particle may be used for applications that require the particle to be responsive to environmental conditions. The biological particles alleviate this major concern while retaining many of the benefits of using bacterial cells. They are:

- Nonreplicating: Their lack of chromosomal DNA means minicells cannot replicate and cause infection, yet they still retain surface proteins and express plasmid genes.
- Modular: Since their plasma membranes are derived from the parent cell, minicells have the potential to retain membrane proteins originally expressed by the parent bacteria.

- Small: At 400 nm, E. coli minicells are much smaller than their parental cells so they can be separated from their parent cells with ease.
- Nonleaky: Minicells have stable, non-leaky membranes and inherit the cytosolic composition of their parent cell, maintaining protein and ion concentrations.

AgroSpheres is the first demonstration of our biological particle use in the environment. While the pesticide degradation application has a real addressable market in the wine production industry and the broader agricultural industry, the parallel goal of AgroSpheres is to demonstrate the usability and safety of our particle in the environment. We want to fully develop the modularity of this platform technology in order to develop further applications, however we are currently focused on scaling up manufacturing to a level where we can conduct field testing for our pesticide degradation device. We anticipate preliminary scale-up field-testing results by the end of summer 2016. AgroSpheres is an integrated platform technology with relatively low R&D costs that has the ability to develop applications with an enormous impact and an enormous return on investment, both economically and societally.

Our team is composed of Dr. Mark Kester, the director of nanoSTAR Institute at UVA specializing in novel drug delivery platforms and a serial entrepreneur serving as the Chief Scientific Officer; Shaun Moshasha, a biotechnology entrepreneur; and Payam Pourtaheri and Ameer Shakeel, undergraduate engineering students serving as the R&D leads. Cumulatively, they have been working to develop the platform technology since May 2013.

From:	Kunickis, Sheryl - OSEC
To:	Covell, Stephen -FS; Bates, Samantha - APHIS; Schwartz, Paul - ARS; Gerlach, Erik - NASS; Martin, Caitrin - FAS; Chin, Teung; Warren, Jim E - APHIS; Johnston, John - FSIS; James, Rosalind; Abel, Sidney W - APHIS; Shimmin, Scott - NASS; Abbott, Linda - OCE; O"Toole, Susan J - APHIS; Kunickis, Sheryl - ARS; Schechtman, Michael; Fajardo, Julius; Martinez, Ernesto - RMA; Fowler, Dianne; Widman, Norm - NRCS, Washington, DC; Haynes, Diana - AMS; JonesKing, Stacy - AMS; Anandaraman, Neena - FSIS; Epstein, David; Schroeder, Jill; Bailey, Melissa - AMS; Fitzner, Michael - NIFA; Koehler, Susan M - APHIS; Domesle, Alexander - ARS; Bronsky, Kathryn E - APHIS; Pattillo, Devon - AMS; Lewis, Paul I - AMS; Caldera, Mayra - FAS; Rasmussen, Mark - FAS; Hyberg, Skip - OSEC; Hill2, Elizabeth - ARS; Haines, Lindsay - NRCS, Washington, DC; Pappas, Chris - AMS; Hackett, Kevin
Cc:	Richard, Keigwin
Subject:	FW: Brown Bag Seminar: University of Virginia Presentation on "AgroSpheres a particle that degrades residual pesticides on the surface of produce"
Date:	Tuesday, September 13, 2016 9:02:07 AM
Attachments:	AgroSpheres- synopsis.docx

Good Morning,
EPA is hosting a Brown Bag Seminar on a topic that is fascinating - and has invited USDA to participate. See the request below and the attachment. (Note I had difficulty with the Doodle poll using my govt computer, but it worked fine on my govt IPad.) Please share with others in USDA that may be interested.

Sheryl

From: Keigwin, Richard
Subject: Brown Bag Seminar: University of Virginia Presentation on "AgroSpheres a particle that degrades residual pesticides on the surface of produce"

As I mentioned, EPA has been approached by two engineering students at the University of Virginia who would like to make a presentation to EPA, FDA, and USDA regarding a product that they've developed that may have the potential to degrade pesticide residues on produce. EPA is happy to host the presentation at our facility in Arlington, VA; people can also participate via teleconference. Please see the link below that connects to a Doodle poll in hopes of finding the best day that works for all three agencies. If you think others would be interested in hearing the presentation, please send the link to those individuals as well. If possible, please respond to the Doodle poll by COB next Friday (September 16th) so that the UVA students can make arrangements to travel to the DC area.

They've sent a backgrounder (attached) to provide you with some additional information about their project.

http://doodle.com/poll/334bzw8s2tsrpe6e

Rick Keigwin
Deputy Director for Programs
Office of Pesticide Programs
US Environmental Protection Agency

AgroSpheres: The future of Agriculture

AgroSpheres is a non-toxic, environmentally friendly biological particle that degrades residual pesticides on the surface of produce. This device was developed by engineering organophosphate hydrolase (OPH), an enzyme that degrades organophosphate pesticides, onto the surface of an E. coli cell. These E. coli cells were then induced to generate minicells (containing no endogenous genetic material), which retained the OPH on their surface membrane. The resultant product is a biological device that degrades paraoxon but does not proliferate in the environment. Preliminary proof of concept data suggests that we have engineered a minicell that contains functional, catalytically active OPH that degrades organophosphate pesticides on plants.

Initially, AgroSpheres is designed to target three big pain points for the agricultural industry as a whole and for wine producers specifically: exposure to pesticides leading to health risks, inflexible Pre Harvest Intervals (PHIs) that determine the minimum time after pesticide application before harvesting is allowed, and stuck fermentation resulting from residual pesticides killing the yeast during the fermentation process. The major value proposition of AgroSpheres is to degrade residual pesticides on demand, which alleviates the three major pain points for our target market. We have determined that we can use this same platform to degrade DDT, which is commonly used in developing countries to combat malaria-stricken mosquitoes. From our lab tests we have determined that there are other forms of remediation for AgroSpheres. They can be programmed to degrade and/or detect radiation, nerve gas, anthrax, and etc. There are countless applications for this platform technology.

Our biological particle is a modular platform technology that can be applied within many contexts; our robust intellectual property position is based upon the design of unique plasmids and unique applications. While the first proof of concept prototype has been developed to degrade organophosphate pesticides like Malathion, the first commercial product will be designed to degrade sprays such as Mancozeb, Captan, and Revus Top. Mancozeb is a cheap, broad spectrum pesticide that wine producers would love to use. Unfortunately, the PHI of Mancozeb is 66 days, which limits its use to the first half of the growing season. During the R&D of AgroSpheres, we will be building our expertise in our platform technology and of the regulatory landscape so that future agriculture and biotechnology applications will have a much lower barrier to entry.

Bacteria have several properties that would make them useful vectors: They are readily engineered, easily grown, and stable in the environment. However, the use of genetically modified bacteria in the environment is riddled with issues, such as the proliferation and horizontal gene transfer of engineered DNA. The biological particles are the result of aberrant cell division in bacteria that yields a normal parent cell and an achromosomal “cell”. Because they lack chromosomes, they cannot replicate, mutate, or express virulent bacteria genes. However, they still contain and express transfected plasmids, which mean that the biological particle may be used for applications that require the particle to be responsive to environmental conditions. The biological particles alleviate this major concern while retaining many of the benefits of using bacterial cells. They are:

- Nonreplicating: Their lack of chromosomal DNA means minicells cannot replicate and cause infection, yet they still retain surface proteins and express plasmid genes.
- Modular: Since their plasma membranes are derived from the parent cell, minicells have the potential to retain membrane proteins originally expressed by the parent bacteria.

- Small: At 400 nm, E. coli minicells are much smaller than their parental cells so they can be separated from their parent cells with ease.
- Nonleaky: Minicells have stable, non-leaky membranes and inherit the cytosolic composition of their parent cell, maintaining protein and ion concentrations.

AgroSpheres is the first demonstration of our biological particle use in the environment. While the pesticide degradation application has a real addressable market in the wine production industry and the broader agricultural industry, the parallel goal of AgroSpheres is to demonstrate the usability and safety of our particle in the environment. We want to fully develop the modularity of this platform technology in order to develop further applications, however we are currently focused on scaling up manufacturing to a level where we can conduct field testing for our pesticide degradation device. We anticipate preliminary scale-up field-testing results by the end of summer 2016. AgroSpheres is an integrated platform technology with relatively low R&D costs that has the ability to develop applications with an enormous impact and an enormous return on investment, both economically and societally.

Our team is composed of Dr. Mark Kester, the director of nanoSTAR Institute at UVA specializing in novel drug delivery platforms and a serial entrepreneur serving as the Chief Scientific Officer; Shaun Moshasha, a biotechnology entrepreneur; and Payam Pourtaheri and Ameer Shakeel, undergraduate engineering students serving as the R&D leads. Cumulatively, they have been working to develop the platform technology since May 2013.